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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/070,099	05/28/1993	KAREL NEWMAN	9197-008710	8455

7590 02/24/2004

BRIAN W. POOR
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCARDERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 94111

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/070,099	NEWMAN ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appellant's Brief filed on Jan. 29, 1996, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Rejections Withdrawn:

2. The objection to the specification under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e., failing to provide an enabling disclosure and failing to adequately describe the instant invention is withdrawn upon further consideration.

3. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification, is withdrawn upon further consideration.

4. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to claim 9.

5. The rejections of the claims under 35 U.S.C. 103(a) over Smolka in view of Ellis, or over Smolka in view of Galfre are withdrawn upon further consideration.

New Grounds of Rejection:

6. Claim 9 is objected because of potentially confusing wording. Specifically, the following phrase needs correction: "(a) contacting the sample with a known amount of labeled intrinsic factor and a known amount of an antibody bound to a solid phase which specifically binds to intrinsic factor...". A suggested correction is the following: "(a) contacting the sample with a known amount of labeled intrinsic factor and a known amount of an antibody bound to a solid phase [which], wherein the antibody specifically binds to intrinsic factor..."

7. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite because claims 1, 2, 5, 7 and 9 contain the phrase "being released from binding in the presence and upon the binding, of vitamin B12 to intrinsic factor". This phrase is confusing in view of the fact that all antibodies and cognate antigens are in a state of equilibrium where the antigen is continuously unbound and then rebound to the antibody. Therefore, the phrase fails to be a useful limitation. Applicants' attention is directed to the

language in the specification on page 22, where the specification teaches that one physical property of the antibodies of the invention is that antibodies described in the specification exhibit an increase in the first order dissociation rate of the antibody-Intrinsic factor complex upon the addition of vitamin B12 and that the dissociation rate is directly dependent on the concentration of vitamin B12.

Claim 7 is indefinite because the preamble of the claimed method is not correlated with the method steps. Specifically, the preamble is drawn to a method of obtaining a monoclonal antibody capable of binding to intrinsic factor only in the absence of vitamin B12, and being released from binding in the presence, and upon the binding, of vitamin B12 to intrinsic factor; whereas, the method results in the isolation of hybridomas that secrete antibodies which bound to intrinsic factor only in the absence of vitamin B12.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrido-Pinson (Journal of Immunology, 97(6): pages 897-912, 1966; cited in the IDS) or Samloff (Journal of Immunology, 101(3): 578-586, 1968).

Claims 1 and 2 are interpreted as drawn to compositions comprising an antibody, to an antibody, wherein the antibody binds to intrinsic factor only in the absence of vitamin B12. The further limitation that the antibody is capable of "being released from binding in the presence and upon the binding, of vitamin B12 to intrinsic factor", is not considered a limitation with which to compare the claimed invention with the prior art, because this phrase is indefinite as explained above in #7. Furthermore, the claim does not stipulate the conditions under which the "release of binding occurs". For example if a very large excess of B12 were to be added to an

antibody-intrinsic factor complex, where the antibody where a competitive antibody, it would appear that the antibody had been "released" from binding. In the case of claim 2, the preamble setting forth the claimed invention as an antibody contained within a kit, is not accorded patentable weight because a kit is interpreted to be a recitation of an intended use for the claimed antibody.

Garrido-Pinson teaches antibodies that bind to intrinsic factor, and specifically teaches "blocking antibodies" that cannot bind to intrinsic factor in the presence of B12 (see page 907-908, especially page 908, 2nd col.). Because the antibodies of Garrido-Pinson do not bind to intrinsic factor in the presence of B12, the limitation that that the antibody binds to intrinsic factor only in the absence of vitamin B12 is met. Thus, Garrido-Pinson teaches antibodies that are the same as those claimed. Samloff teaches "blocking" antibodies that bind to IF but not to IF-B12 complex (page 581, 2nd col.). Thus, Samloff teaches antibodies that are the same as those claimed.

Applicants' should note the following: If the limitation "being released from binding in the presence and upon the binding, of vitamin B12 to intrinsic factor" were to be replaced by a phrase that obviated the rejection under 112, 2nd, the claimed antibodies might still read on the prior art. This is because the claimed antibodies are drawn to compositions comprising antibodies. A "composition comprising an antibody" reads on antisera that contain antibodies with whatever binding characteristics are recited in the claim regardless of whether those characteristics are taught in the prior art. In the instant case, for example, Garrido-Pinson teaches a genus of "blocking antibodies", where some of these antibodies would be those that fail to bind to intrinsic in the presence of B12 because of the mechanism described in the

specification, and where some others of these antibodies would be those that blocked because they are compete with B12 for binding to intrinsic factor. One suggestion for obviating a rejection over Garrido-Pinson would be to limit claims to a monoclonal antibody.

9. Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pourfazaneh-I (WO 91/00519; published 10 January 1991; cited in the IDS). Applicants' should note that the filing date of the instant application (5/28/1993) is used for purposes of comparing the claimed inventions with the prior art, because the parent application from which the instant application is a continuation-in-part fails to specifically teach antibodies that fail to bind to intrinsic factor in the presence of B12. Therefore, the limitations of the instant claims do not find support in the continuation-in-part parent.

Claims 1-6 are drawn to antibodies and kits comprising said antibodies, where the antibodies bind to intrinsic factor only in the absence of vitamin B12. The kits may include an antibody that binds to intrinsic factor regardless of the presence of vitamin B12. Anti-intrinsic factor antibodies that bind to intrinsic factor only in the absence of vitamin B12 read on competitive antibodies. Claims 9 and 10 are drawn to methods for the assay of vitamin B12 in a liquid samples comprising the use of an antibody that binds to intrinsic factor that bind only in the absence of vitamin B12.

Pourfazaneh-I teaches antibodies and monoclonal antibodies that bind to intrinsic factor, where the antibodies are competitive antibodies (see abstract and page 5, lines 8-15; page 6, line 13 – page 10, line 23. Competitive antibodies are antibodies that would bind to intrinsic factor only in the absence of vitamin B12. Additionally, Pourfazaneh-I teaches a monoclonal antibody

that binds to intrinsic factor alone (see page 18, line 37 – page 19, line 1). Thus, Pourfazaneh-I teaches antibodies, kits and methods that are the same as that claimed.

10. Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Pourfazaneh-II (U.S. 5,310,656; issued May 10 1994).

Pourfazaneh-II teaches antibodies and monoclonal antibodies that bind to intrinsic factor, where the antibodies are competitive antibodies (see abstract and col. 3, lines 21- 34; claim 1). Additionally, Pourfazaneh-II teaches a monoclonal antibody that binds to intrinsic factor alone (col. 10, lines 17-18). Thus, Pourfazaneh-II teaches antibodies, kits and methods that are the same as that claimed.

Claim Rejections Maintained:

11. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Smolka (Gastroenterology 98: 607-614, 1990) is maintained.

This rejection is maintained because, as discussed above, the claimed antibodies read on competitive (or "blocking") antibodies. Smolka teaches monoclonal antibodies to intrinsic factor that appear to inhibit the binding of cobalamin by intrinsic factor (see abstract). Therefore, as discussed previously, such antibodies would also be blocked from binding to intrinsic factor in the presence of vitamin B12. Thus, Smolka teaches antibodies that are the same as that claimed.

Conclusion

No claim is allowed. Claims 7 and 8 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 8:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Anne L. Holleran
Patent Examiner
February 20, 2004

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600